



Commentary

Mandatory Newborn Screening for Human Immunodeficiency Virus

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Pediatricians, responsible for the care of children infected with the human immunodeficiency virus (HIV), increasingly voice concern that the first indication of a child's illness owing to this deadly virus is a fatal infection in the first months of life. Some of these health professionals believe that early identification of children at risk for the development of HIV infection, and the initiation of prophylactic therapies, will greatly enhance the quality and quantity of children's lives. This has resulted in the recommendation that the standard newborn screening test done on all babies right after birth, which presently identifies several genetic and metabolic disorders, be used to find those children at risk for HIV infection. This was the basis for New York Assembly Bill 6747, proposed in June 1993 by Assemblywoman Nettie Myerson.

At the present time in New York State, as well as in the majority of other states in the United States, in addition to the routine blood tests that are performed in the first few days of life, a screening test for the HIV antibody in the newborn's blood is also being done to determine the prevalence of this infection in women giving birth. The antibodies present in the newborn's blood have been passively transferred from the mother and signify unequivocal evidence of HIV infection in the woman and a 15% to

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30% risk of actual infection in the baby.¹ At this time it is not possible to identify, at birth, which newborns are actually infected. Testing for virus and viral components allows the identification of some infected neonates at birth, and virtually all infected infants can be identified by 3 months of age.² Thus, antibody testing of newborns identifies a cohort of infants who will require further study and evaluation to ascertain whether they are infected. In New York State, approximately 1,800 to 1,900 (0.6%) of the 300,000 babies born each year have HIV antibodies found in their blood.³

This seroprevalence study has been used by public health officials to track the HIV epidemic and to understand better the resources that must be deployed for the care of infected women and children. However, some professionals believe that it would be appropriate to change this public health surveillance tool into a universal case identification program. Thus, medical professionals, public health officials, and legislators have proposed mandatory, universal screening of newborns for HIV as a part of the state-mandated newborn blood test. These observers have argued that, because the test is already being performed for epidemiological purposes, it would be easy to link the test to the patient and report the newborn's HIV status to his or her parents and health care provider.

At first glance these recommendations seem both well-meaning and reasonable in that the goal of protecting children from inappropriate death and disability is certainly laudable. However, there are many questions to be raised about the basic assumptions upon which these recommendations are made, as well as serious concerns about the consequences of universal nonconsensual screening of newborns for HIV. There are many unique aspects, never previously considered in newborn screening programs, which emerge in the case of screening newborns for HIV. Presently, large population-based laboratory screening programs for HIV measure antibody levels in blood specimens. In the case of newborn screening for HIV antibodies, a positive test would reflect the fact that the woman who has given birth to this baby has been infected with

HIV and has passed the antibodies to her newborn. A small proportion of the babies who test positive for antibody will be infected (15% to 30%) while 100% of these infants' mothers will have the disease. Three quarters or more of the infants who are antibody-positive and at risk for HIV will not have the disease and yet will suffer the consequences along with the potential benefits of being identified. In addition, all of the women who will be informed that their babies have the potential to be infected will in fact be infected and will require counseling, further evaluation, and intervention for their own illnesses.

Some have argued that identifying women who heretofore had not known of their illness would be a major positive benefit, in that these women could receive necessary counseling and services to enhance their future longevity and quality of life. This hope for medical benefit, however, has not been confirmed in recent studies of asymptomatic HIV patients.⁴ It would, however, be possible for the identified women to make reasonable choices about behaviors related to the transmission of HIV to others and in the planning of future pregnancies. Many have noted with concern that there are inadequate services available for the care of women identified as HIV-infected. Furthermore, because of the serious social consequences of the stigma associated with being identified as HIV-infected, the women and their infants might be discriminated against and run the risk of losing jobs, friends, family relations, and even housing and other basic economic supports.

While being sensitive to these important potential consequences to women who are identified as HIV-infected, concerned advocates for the children continue to point out that these social implications should not outweigh concern for the potential for inappropriate treatment and even death of an unidentified infant. They often neglect to take into account, however, that identification is only the beginning of a long-term relationship between the infant and family and the health care system. If the fear of stigmatization and discrimination causes women not to comply with recommended assessments and interventions for themselves

and their newborns, the sought-after goal of protecting the interests of the HIV-infected infants will not be attained.

In addition to the fear that women may appropriately have about being discovered by their community as HIV-infected, many also may have fears of being discovered by the health care establishment. Since the HIV epidemic in women of child-bearing age is highly associated with intravenous drug use or partnering with people who are intravenous drug users, there is a basic underlying fear that the revelation that a woman is HIV-infected will result in investigations which will determine that the woman has used illicit substances and thus may not be considered an adequate mother for her newborn. There is an increasing national trend toward criminalization of substance use in pregnancy as well as presumptions by some in the health care professions that the use of illicit substances during pregnancy is sufficient evidence to take an infant away from its mother after birth. Although New York State has been careful not to equate evidence of substance use with the conclusion that a woman is an unfit mother, women still are very fearful of being labeled as users of illicit substances. Therefore, a woman who is revealed to be HIV-infected through the nonconsensual testing of her newborn might well fear that her baby will be taken away from her because of the association of HIV and use of illicit substances. Some professionals are concerned that mandatory newborn screening for HIV may result in women and infants fleeing from the health care system and going underground in an attempt to avoid the punitive aspects of what may be perceived as a hostile health care environment. This avoidance of the health care system could affect even women and infants who are HIV-negative and fear coming forward to learn their HIV status.

This concern has been one of the major arguments by those who have opposed mandatory nonconsensual screening of newborns. They argue that it would be critically important to develop an atmosphere of trust, which can only be provided through the counseling of women concerning the importance of screening themselves and their newborns and the availability of treatment

services that would attempt to enhance the mother-infant dyad rather than potentially disrupt it.

Another argument by those who have opposed the mandatory screening of newborns for HIV has been analysis of the data concerning the efficacy of mandatory screening to actually prevent HIV infection or prolong asymptomatic incubation periods or prevent infectious complications of HIV. The only benefit that newborn screening could provide to actual primary prevention of HIV infection to that particular newborn would be the strong recommendation that the mother who is HIV-infected not breast-feed her newborn, who might not yet be infected with the virus and who could potentially become infected thereby. Some data from international studies report incremental transmission of HIV from women to their infants through breast-feeding.⁵ Two specific aspects of HIV screening of newborns make the likelihood of protecting infants from infection with the HIV virus small. First, only a small percentage of the women who are HIV-positive and unaware of this infection elect to breast-feed their newborns. These women are generally intravenous drug users who rarely wish to consider breast-feeding and are, in addition, counseled to not breast-feed because of the drugs. Secondly, even if the screening program were effective and reasonably rapid, it is unlikely that, at least with the present accepted technologies, a woman could be told she was HIV-infected earlier than several weeks after the birth of her newborn. Thus, if she had elected to breast-feed her infant, she would have already been doing that for a significant period of time. Some scientists believe that if the infant will be infected via breast-feeding, the immature gut is most susceptible to viral transmission in the first weeks of life. Therefore, primary prevention of HIV infection through mandatory newborn screening seems to be relatively far less important than the potential secondary prevention that may accrue from the early identification of an already infected newborn. Secondary prevention is provided by attempts to prolong the period of symptom-free disease or the initiation of prophylactic therapies to prevent complications of the disease.

At present, there are no studies that support the use of anti-retroviral agents as beneficial for prolonging the incubation period of asymptomatic infants. There are many studies in progress which, it is hoped, will result in findings that enhance the quality and quantity of asymptomatic life for HIV-infected children; however, to date no treatment has been found effective in accomplishing this goal. There is, however, one preventive intervention that virtually all clinicians agree is effective. This is the use of prophylactic antibiotics to prevent *Pneumocystis carinii* pneumonia, a devastating and often lethal infection in infants with HIV. Most clinicians who care for HIV-infected infants initiate prophylaxis within the first 2 months of life. This practice has resulted in a decrease in *P. carinii* pneumonia in the first year of life in HIV-infected children. However, what is not known is whether these same children who are now not becoming infected with *P. carinii* pneumonia are developing other serious manifestations of HIV disease because of their immunocompromised state. Thus, clinicians and public health officials alike are unable to define the actual long-term benefit of the *P. carinii* prophylaxis regimen to the children. Pediatricians argue, however, that there are some individual babies whose lives are saved and who do benefit from this early initiation of antibiotic therapy. The exact number of children benefited, in terms of their long-term quality and quantity of life, is unknown.

The focus solely on the interests of the infants as a rationale for mandatory newborn screening, however, ignores the fact that the rights and interests of the mothers will be affected markedly. Adults have the right to expect the law to protect their rights and the ethical precepts of medicine to protect their interests.

Since 1905, public health authorities and state legislatures have had the right to create regulations and laws under certain circumstances to intrude into the lives of individuals in the name of public safety and public welfare.⁶ Routine screening of newborns, with revelation of test results without parental consent for a series of conditions that are potentially life-threatening or

health-impairing, is one such state-mandated intervention that has passed constitutional scrutiny.⁷

It is only within the last 20 years that states have invoked mandatory newborn screening to protect infants from inherited diseases such as phenylketonuria, maple syrup urine disease, hypothyroidism, sickle cell anemia, and others. The legal and ethical bases upon which states impose these programs on families are the considerations that the state has an ethical obligation to prevent or relieve serious illness in its children and that this obligation precludes parental discretion to choose whether or not to have their newborn tested. Screening for specific disease entities has been justified if there is a reliable, sensitive, and specific test to diagnose the condition before substantial harm can occur to the newborn. In addition, in order to justify the mandatory nature of the testing, there must be an available and effective presymptomatic treatment or intervention for the disease or its consequences. A program for tracking and follow-up of the children who are identified, and counseling of the families of the children, are also required. Historically, it has been clear that the mere identification via a laboratory test of an individual newborn affected with an illness does not assure that that child will be found and provided with the necessary medical evaluations and treatments required, nor does identification assure that a family will understand the meaning of the laboratory test, the importance of the follow-up assessments, or the need for the presymptomatic interventions.

Mandatory newborn screening has a major impact on two legal principles concerning personal choice: confidentiality and informed consent. The ancient oath-based concept of confidentiality and the state statutes that govern its present form require that the medical profession maintain the privacy of physician-patient communication and not reveal to others information obtained in this important relationship. The most commonly cited reason for the existence of this principle is the need to encourage patients to provide all relevant facts about their medical history and symptoms, so that the physician would be best able to assist them. The principle also places the obligation upon the physician to protect

the secrets of the patient. The concept of confidentiality was never seen as absolute; it could be breached under specific circumstances. Infringement of the principle was most often based on the need to protect the patient from himself or herself as well as to protect the public health, or even to protect an identifiable third person put at specific risk from the patient's plans or ability to do harm.⁸ Even if a reporting system for newborn HIV results could adequately deal with issues of confidentiality, and this is quite difficult to conceive, concerns about informed consent would still have to be addressed.

The principle of informed consent includes the duty of the physician to provide, and the right of the patient to receive, appropriate and sufficient information to make an informed choice concerning recommended evaluations and treatments.⁹ In addition, respect for the principle of informed consent is widely considered to be essential in enlisting the patient's cooperation, which is necessary if behavior modification or compliance with treatment is expected.¹⁰ New York State law has been quite explicit concerning the statutory requirement of informed and counseled consent before and after HIV testing. New York State law also specifically governs the circumstances in which disclosure of confidential information concerning HIV status is allowed.¹¹ Because screening of the newborn in fact determines the HIV infection status of the mother, many have argued that the doctrine of informed consent would be breached if newborns were tested without counseling and informing of the women and obtaining their permission.

However, there are considerations in addition to individual choice. For almost 70 years, the United States Supreme Court has held that, pursuant to its authority to protect public welfare, the state may use its police power to compel certain public health interventions, such as vaccinations, without the consent or over the objection of citizens.⁶ It is now unquestioned that public health authorities have the right under certain circumstances to intrude into the lives of individuals in the name of public safety and welfare, with mandatory reporting of certain illnesses being

one such instance. Courts have said that the public health authorities must balance the state's objective in intervening against the individual rights thereby infringed upon. In addition, when fundamental rights are implicated, public health intervention must be bound by the doctrine of "least restrictive alternative,"¹² which insists that policies must be crafted to achieve the desired goal with the least intrusion into the lives of the persons affected. On the other hand, the courts have also held that states have "broad latitude in experimenting with possible solutions to problems of vital local concern."¹³

Although the state potentially has wide authority in the area of newborn screening, the substantive right to privacy is critically important in the case of HIV because the women are being screened as well. The right to privacy has two components: the right of independent decision-making (privacy as autonomy) and the right of selective disclosure (privacy as information control).¹⁴ Both of these aspects of the right to privacy are dramatically affected by mandatory HIV screening of newborns. Although the Supreme Court has held that adults have a right to be left alone, it has recently permitted involuntary testing of adults, such as drug testing of railroad workers after an accident.¹⁵ These tests are for the benefit of others than those tested and may provide grounding for testing newborns.

In addition to these basic legal principles, there are potential legal ramifications of mandatory newborn screening in the area of equal protection under the law, which is guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution. Because government-created classifications are required to be fair and equitable, they are subjected to special inquiry. Those classifications that historically have been used unfairly, such as race and gender, receive heightened scrutiny. Since women would be tested through mandatory newborn screening, any such law would have to defend the reasons for differentiating these women from men as well as from other hospitalized patients. In addition, because of the demographics of the HIV-infected population, the

legislation would have to defend the right to treat differently a group composed primarily of women of color.

An additional legal concern is the implication of the recent United States Americans with Disabilities Act (1990). Because the legislative history of the Act clearly indicates the intent to include communicable diseases and infections within the definition of disability, women who would be identified as HIV-infected would presumably be protected from being treated differently from other persons who are infected.¹⁶ Thus, some might argue that these women were inappropriately being discriminated against by non-consensual testing.

In summary, the legal implications of mandatory newborn screening for HIV are multiple, and any proposed legislation would need to address these legal questions and survive potential challenges. It is by no means certain that a statute to involuntarily screen newborns for HIV would be found unconstitutional, but any such legislation would clearly be carefully scrutinized by legal experts and challenged by legal advocates.

A different legal argument and ethical analysis, which some believe should support the authority of the state to perform mandatory newborn HIV screening, is found in the New York Family Court Act, which supports the right of the state to protect its children from irresponsible decision-making by parents. The Act provides the authority to intervene without consent over the objection of a parent when a child's physical, mental, or emotional well-being is in danger of impairment because of parental failure to provide necessities including medical care.¹⁷ This law requires an individual determination that a particular child is being neglected by a particular parent who is financially capable but refuses to meet the child's need. It does not create a general or categorical notion of a standard of medical neglect. Notwithstanding traditional reluctance to override parental rights to make health care decisions on behalf of their children, courts have upheld the state's right to intervene when necessary medical care is withheld. The state's ability to intercede on behalf of any

presumably medically neglected child is thus established in both case law and statute.

For many years, pediatricians have argued that parental discretion in making choices concerning the health care of children should not be absolute. Although physicians, in general, respect the right and authority of parents to make choices for the health care of their children, the medical professional has an independent obligation to each child to advocate the course of treatment deemed to be in that child's interest. These beneficence-based obligations require the physician to seek court intervention to assure that needed efficacious treatment is given to an individual child whose parents refuse to grant permission. The ethical principle that has evolved to justify this intrusion into family privacy is the principle of the "best interests of the child." Parents and physicians are obligated to make choices which reflect the best interests of the child, while acknowledging that what is actually in the interest of an individual child may at times be uncertain.

Some pediatricians claim that it is in the best interests of individual children who are HIV-infected to be identified as early as possible so that they can receive needed evaluation and treatment. Thus, they argue that parental authority to choose whether a child is screened for HIV should be precluded. It is hard to disagree that the medical health of a child might be enhanced by knowing that he or she is HIV-infected. Whether it is in the best interests of an individual child to be labeled HIV-infected or at risk for HIV infection remains a question about which reasonable people could have differing opinions.

An analysis that would determine the best interests of an individual child must weigh all the potential positive and negative consequences of that decision. Potential benefits should not be overstated, even by well-meaning individuals, in an attempt to overwhelm the potential negative impact of a decision. In addition, what counts as a positive or negative consequence to an individual child should include an analysis of the impact of the choice on the person most important to that child, the mother. This is particularly true if the decision will potentially cause family

discrimination, isolation, and stigmatization. Wresting the authority away from parents to determine the best interests of their child is fraught with danger and should only be invoked when parents are clearly acting irresponsibly. In the face of honest uncertainty about the best interests of the infant, parents ought to be allowed great discretion in making choices concerning their own child's future.

Those who believe that mandatory newborn screening for HIV is appropriate at this time invoke the argument that it is in the best interests of the individual child to be identified as at risk for HIV infection as early as possible and that mandatory newborn screening of all children is the appropriate way to reach this goal. It remains an issue of debate, however, and of disagreement among reasonable people, as to whether mandatory testing, with all of the potential consequences to mother and infant, is indeed of greater benefit for individual children than other attempts to determine which infants are at risk for HIV infection.

If it was certain that early identification of newborns infected with HIV would definitively result in enhanced quality and quantity of life for a substantial proportion of the infants so identified, and if the process of identification did not result in other noninfected infants being harmed, then it would be ethically appropriate for advocates for children's health to demand and expect that mandatory screening would occur. At the present time, however, this is not the case. The lack of certainty that early identification of HIV infection can enhance quality and quantity of life for infants, and the potential harms to the women and their children that accompany labeling, make us conclude that mandatory newborn screening for HIV, at the present time, is not appropriate.

We began this commentary by defining the problem as the need to identify infants who are HIV-infected as early as possible, to help them and their families cope with this serious illness. The real question is not whether New York State should invoke mandatory newborn screening for HIV, but rather, what methods exist to identify children at risk for HIV infection and to help them and their families. One need not invoke mandatory newborn screening

as the only or the best approach to assure early identification of infants who are HIV-infected. Virtually everyone would agree that knowing the serological status of women of child-bearing age, as well as women who become pregnant, through voluntary counseling and testing would be far preferable to a system of mandatory testing after birth. If programs could be developed for universal voluntary screening of women based on mandatory and appropriate counseling and the availability of necessary family-oriented comprehensive care programs for women infected with HIV and their children whether or not they were infected, then mandatory screening of newborns would be unnecessary. In addition, because much of the primary prevention research focuses on attempting to decrease transmission of HIV from woman to fetus, it would be even more efficacious to know the HIV status of the pregnant woman before or early in pregnancy, to permit her to consider the possibility of transmission as one possible consequence of her pregnancy.

Programs that counsel all pregnant women during prenatal care or immediately after the delivery of their baby, about the importance and benefits of knowing their and their newborn's HIV status, are presently in place. These comprehensive initiatives have resulted in more than 90% of the infants at risk for infection being identified and engaged in needed follow-up services. In addition, the women identified as infected are offered appropriate care. These successful reports must be contrasted with mandatory screening, which has the potential to identify a newborn at risk for HIV but carries with it the subsequent inability to locate the child or enroll that child in follow-up evaluation and treatment because of the various aspects of fear and discrimination discussed above.

Perhaps most critically important in the analysis of this complex problem is the issue of trust and respect among health care professionals, their patients, and the public at large. We need not create an atmosphere of fear and coercion when we have the opportunity to develop a program of screening and therapy that is both voluntary and comprehensive and has the likelihood to result in benefiting the vast majority of those in need. We have available

today a potential method, through mandatory counseling and aggressively encouraged testing of women, to identify virtually all of the infants who are at risk for HIV infection. With appropriate resources given to education and health care delivery, the desired goal of early identification and treatment of HIV infected infants can be accomplished without breaching legal doctrines or violating ethical principles.

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